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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/657,144	09/09/2003	David Alexander	IMMR-IMD0002E	1898
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IMMERSION -THELEN REID BROWN RAYSMAN & STEINER LLP			EXAMINER	
P.O. BOX 640640			GISHNOCK, NIKOLAI A	
SAN JOSE, CA 95164-0640				
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/657,144	Applicant(s) ALEXANDER ET AL.	
	Examiner Nikolai A. Gishnock	Art Unit 3714	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 19 July 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 17, 24, 25, 27, 28 and 32-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 17, 24, 25, 27, 28 and 32-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 09 September 2003 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>9/21/2007</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

In response to the Applicant's response of 7/19/2007, claims 1-16, 18-23, 26, 29-31, 39, & 40 are cancelled. Claims 17, 24, 25, 27, 28, & 32-38 are pending.

Allowable Subject Matter

1. The finality of the last Office action is hereby withdrawn. Further, the indicated allowability of claims 17, 24-28, & 32-38 is withdrawn in view of the newly discovered reference(s) to Carlson et al. (US 5,820,600). Rejections based on the newly cited reference(s) follow. The Applicant's amendments, filed 7/19/2007, have been entered.

Priority

2. Applicant's claim for the benefit of a prior-filed application under 35 U.S.C. 119(e) or under 35 U.S.C. 120, 121, or 365(c) is acknowledged. Applicant has not complied with one or more conditions for receiving the benefit of an earlier filing date under 35 U.S.C. 102 as follows:

The later-filed application must be an application for a patent for an invention that is also disclosed in the prior application (the parent or original nonprovisional application or provisional application). The disclosure of the invention in the parent application and in the later-filed application must be sufficient to comply with the requirements of the first paragraph of 35 U.S.C. 112. See *Transco Products, Inc. v. Performance Contracting, Inc.*, 38 F.3d 551, 32 USPQ2d 1077 (Fed. Cir. 1994).

The disclosure of the prior-filed application, Application No. 08/923,477, fails to provide adequate support or enablement in the manner provided by the first paragraph of 35 U.S.C. 112 for all the claims of this application. The prior filed application bears no mention of, among other

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features, the retainer and ring configuration or of a pivotable mock anatomical site. As such, the application has been given a date of 1/28/1998, commensurate with the filing of the instant application. In the response, Applicant recites that the 08/923,477 application provides adequate support for the above-mentioned feature. However, Applicant fails to cite exactly where such support is specified and as such, the objection to the priority claim stands.

Drawings

3. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the second or further locking mechanism, utilizing pressure and/or frictional forces to prevent rotation via ring must be shown, or the feature(s) canceled from the claim(s). *No new matter should be entered.*

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the examiner does not accept the changes, the applicant will be notified and informed of any required corrective action in the next Office action. *The objection to the drawings will not be held in abeyance.*

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

4. Claims 17, 24, 25, 27, 28, & 32-38 are rejected under 35 U.S.C. 103(a) as being unpatentable over Younker (US 5,951,301), hereinafter known as Younker, in view of Carlson et al. (US 5,820,600), hereinafter known as Carlson.

5. Younker teaches an apparatus for simulation (anatomical simulator system, 4:24-38) comprising: a housing (synthetic torso resting on a base, Figure 1, Items 12 & 14, also 4:24-38); a mock anatomical site coupled to the housing (the torso includes a pneumoperitoneum wall that defines a plurality of trocar apertures, 4:24-38; these trocar apertures are understood to be mock anatomical sites), the mock anatomical site being pivotable (mounting portion has an axial thickness and diameter that are predetermined to enable realistic movement of inserted trocars and instruments inserted there through, to mimic the movement and feel of trocars and instruments inserted into actual human peritoneum cavities, and flex during this pivotal movement of the trocars; the dimensions of the mounting portion are determined such that the trocar and trocar stop can pivot about the point of insertion through the aperture in all directions upon the exertion of manual force equivalent to that required to deflect a trocar the same extent in an actual human peritoneum, 5:25-35), having an orifice (trocar stop for a trocar, Figure 1, Item 24, each trocar aperture is sized to receive a standard trocar stop into which trocars may be inserted. 4:24-38), the orifice being configured to receive a peripheral device (endoscopic instruments can be inserted through the trocars into the interior cavity for manipulation, incisions

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and dissection of the anatomic structure formed in the procedure pack, 4:24-38); the mock anatomical site being functionally coupled to a pivotable torsion tube (a trocar, Figure 1, Item 22; also 4:24-38); a resiliency-providing material disposed proximate to the orifice and the housing (gastro-intestinal procedure pack, Figure 1, Item 20; also 4:24-54), between the mock anatomical site and a sensing assembly (the procedure pack also includes an electrode mounted in electrical contact on the stomach that is connected to a lead that passes from the tray for use in electrocauterization training; 4:56-60; also Figure 2, Items 52 & 54; the electrode, electrical contact, and lead are understood to be a sensing assembly; further the procedure pack provides sensory tactile feedback to a trainee, as in 5:54-65; this is further understood to be a sensing assembly) [Claims 17, 24, 28, 32, 35, & 37].

6. What Younker fails to teach is a first retainer; a first ring disposed proximate to the orifice, the first ring being configured to rotate about the first retainer; a first locking mechanism configured to prevent movement of the orifice when the locking mechanism is engaged in a locked position; a second retainer; a second ring coupled to the orifice, the second ring being configured to rotate about the second retainer; a second locking mechanism configured to prevent movement of the orifice when the second locking mechanism is engaged in a locked position, and a hollow member extending through the resiliency-providing material and between the orifice and the housing and the sensing assembly, through the first retainer and first ring, the hollow member being configured to guide the peripheral device from the orifice to the housing and the sensing assembly [Claims 17, 24, 28, 32, 35, & 37], and wherein the locking mechanism uses at least one of a frictional force and a pressure force to prevent the movement of the orifice [Claims 27 & 34]. However, Carlson teaches an adjustable trocar valve (the valve is attached to the proximal end of a cannula shaft to form part of an introducer assembly, such as a trocar or a radially expandable introducer, for introducing instruments and viewing scopes

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through a percutaneous penetration into a patient's body, 4:15-19) having a first retainer (pivot tower, Figures 1 & 4, Item 40); a first ring disposed proximate to the orifice (dialator ring, Figures 1 & 4, Item 50), the first ring being configured to rotate about the first retainer (a second valve member or dialator ring is movably coupled around pivot tower, 7:34-49; also, 4:37-46); a first locking mechanism (holding members, Figures 5A & 5B, Item 110) configured to prevent movement of the orifice when the locking mechanism is engaged in a locked position (the valve further includes means for securing a proximal portion of the instrument at or near the center of the membrane; the securing means comprises one or more holding members coupled to the first valve member for preventing transverse movement of the instrument relative to the membrane, while allowing axial movement, 4:47-55; thus preventing movement of the membrane, being part of the trocar and trocar stop assembly, e.g. the orifice, when secured, while the instrument is moved), and a hollow member (introducer assembly including cannula shaft, Figure 1, Items 2 & 4) extending through the resiliency-providing material and between the orifice and the housing and the sensing assembly, through the first retainer and first ring, the hollow member being configured to guide the peripheral device from the orifice to the housing and the sensing assembly (introducer assembly generally includes an elongate shaft or cannula, a handle and a valve assembly; cannula has a proximal end, a distal end, and an axial lumen there between for receiving elongate objects, such as an endoscope and/or surgical instruments for performing a surgical procedure within the patient's body, 7:5-23), and wherein the locking mechanism uses at least one of a frictional force and a pressure force to prevent the movement of the orifice (Holding members are biased radially inward by a suitable biasing means, such as a spring, so that members secure the instrument at the center of membrane, 10:13-16; it is understood that the spring exerts a pressure force on the trocar and trocar stop, which is countered by friction from a normal force against the simulated instrument). The trocar

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and valve assembly of Carlson would be inserted into the trocar aperture of Younker during a surgical simulation. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have included a first retainer; a first ring disposed proximate to the orifice, the first ring being configured to rotate about the first retainer; a first locking mechanism configured to prevent movement of the orifice when the locking mechanism is engaged in a locked position, and a hollow member extending through the resiliency-providing material and between the orifice and the housing and the sensing assembly, through the first retainer and first ring, the hollow member being configured to guide the peripheral device from the orifice to the housing and the sensing assembly and wherein the locking mechanism uses at least one of a frictional force and a pressure force to prevent the movement of the orifice, of the trocar as taught by Carlson, in the mock anatomical site in the apparatus for simulation of Younker, in order to increase the realism and accuracy of the training simulation [Claims 17, 24, 27, 28, 32, 34, 35, & 37],

7. What Younker and Carlson further fail to teach is a second retainer; a second ring coupled to the orifice, the second ring being configured to rotate about the second retainer; a second locking mechanism configured to prevent movement of the orifice when the second locking mechanism is engaged in a locked position [Claims 17 & 28]. However, Carlson teaches these elements, at least at 4:37-55 and 7:34-49, as treated above. The court has held that the mere duplication of parts has no patentable significance unless a new and unexpected result is produced. See *In re Harza*, 274 F.2d 669, 124 USPQ 378 (CCPA 1960). In the instant case, support for the finding of a new and unexpected result for using a second retainer, ring, and locking mechanism over the advantages disclosed for the first retainer, ring, and locking mechanism was not found in the applicant's specification. Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have included a

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second retainer; a second ring coupled to the orifice, the second ring being configured to rotate about the second retainer; a second locking mechanism configured to prevent movement of the orifice when the second locking mechanism is engaged in a locked position, in the apparatus for simulation of Younker, in light of the teachings of Carlson, in order to increase the realism and accuracy of the training simulation [Claims 17 & 28].

8. Younker teaches wherein the block of resilient material is a block of foam (a suitable elastomeric formula for making such a dry suture training procedure pack is a two part expandable urethane foam, 7:19-26) [Claims 25 & 33].

9. Claim 36 is rejected under 35 U.S.C. 103(a) as being unpatentable over Younker, in view of Carlson, as applied to claim 32 above, and further in view of Lang et al. (US 5,480,307), hereinafter known as Lang.

10. Younker and Carlson teach all the features of claim 32, as demonstrated above. Younker teaches where in the housing is a mock torso (synthetic torso resting on a base, Figure 1, Items 12 & 14, also 4:24-38). What Younker and Carlson fail to teach is wherein the mock anatomical site is a mock face [Claim 36]. However, Lang teaches a training and practice apparatus for simulating and practicing clinical processes, having a model bust with a model head (Figure 1, Items 6 & 7), where the mock head has a face (Figure 2, Item 7), and is a mock anatomical site (FIG. 1 shows the model head in a supine disposition, viz. a working position in which clinical dental or orthodontic processes are carried out in the mouth area; this can take place by means of treatment instruments, which are individual treatment tools or treatment equipment connected to supply hoses, 5:8-30). The mock face of Lang would be mounted on the mock torso of Younker, as taught by Lang, to be used by inserting treatment instruments in the mock anatomical site. Therefore, it would have been obvious to one of ordinary skill in the

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art, at the time the invention was made, to have the mock anatomical site be a mock face, as taught by Lang, in the apparatus for simulation of Younker, as taught by Carlson, in order to increase the realism and accuracy of a simulation of facial surgery [Claim 36].

11. Claim 38 is rejected under 35 U.S.C. 103(a) as being unpatentable over Younker, in view of Carlson, as applied to claim 17 above, and further in view of Bailey (US 5,800,179), hereinafter known as Bailey.

12. Younker and Carlson teach all the features of claim 32, as demonstrated above. What Younker and Carlson fail to teach is wherein the peripheral device is a guidewire [Claim 38]. However, Bailey teaches a system for training persons to perform surgical procedures, having a mock surgical instrument (implement), coupled to a movement guide and sensor assembly, which contains a guide wire (the distal end of the implement within the housing is affixed to a movement guide and sensor assembly; collectively, the framed assembly with components described above, guide wire, and the guide rails form the movement guide and sensor assembly, 5:23-49). One of the endoscopic instruments simulated for insertion into the mock body of Younker would be an implement attached to a guide wire, as taught by Bailey.

Therefore, it would have been obvious to one of ordinary skill in the art, at the time the invention was made, to have made the peripheral device of Younker a guide wire, as taught by Bailey, in order to restrict the motion of the implement within the housing and provide accurate sensing of the implement relative to that housing [Claim 38].

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Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nikolai A. Gishnock whose telephone number is 571-272-1420. The examiner can normally be reached on M-F 8:30a-5p.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Xuan M. Thai can be reached on 571-272-7147. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NAG

NAG
9/25/2007

Ronald Laneau

Ronald Laneau
Primary Examiner
Art Unit 3714

9/30/07